UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

GIOVANNA BULOX, MATIAS BULOX, LORENA AHIRI MERLO, and DANIEL MERLO,	§	
Plaintiffs,	§	
v.	§	**Civil Action No. 4:21-CV-02320**
COOPERSURGICAL, INC., FEMCARE, LTD., and UTAH MEDICAL PRODUCTS, INC.,	§	
Defendants.	§	

ORDER ACCEPTING FINDINGS, CONCLUSIONS, AND RECOMMENDATION OF THE UNITED STATES MAGISTRATE JUDGE

Pending before the Court is the March 6, 2025, Report and Recommendation ("R&R") prepared by Magistrate Judge Dena Hanovice Palermo.[1] (Dkt. No. 190). In this lawsuit, Plaintiffs bring several products-liability claims against Defendants under Texas law arising from post-implant complications related to a medical device called the "Filshie Clip." (Dkt. No. 40 at 17– 22, 27–30). Defendants respond that Plaintiffs' state-law claims are preempted because Filshie Clips are federally regulated under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. ch. 9, which generally doesn't allow private enforcement actions, *id.* § 337(a). After reviewing the record and applicable law, Judge Palermo agreed that Plaintiffs' state-law claims are federally preempted. (Dkt. No. 190 at 1).

[1] The Court notes that magistrate judges should be referred to as either magistrate judge or judge—not magistrate.

Judge Palermo made findings and conclusions and recommended that:

(1) Defendants' Motions for Summary Judgment, (Dkt. Nos. 123, 124, 125), be **DENIED AS MOOT** as to Plaintiffs' manufacturing-defect claims and **GRANTED** as to all remaining claims;

(2) Defendants' Motion to Exclude, (Dkt. No. 127), be **DENIED AS MOOT**; and

(3) Plaintiffs' Motions for Summary Judgment, (Dkt. Nos. 134, 135), be **DENIED AS MOOT**.

(Dkt. No. 190 at 18).

The Parties were provided proper notice and the opportunity to object to the R&R. *See* 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b). On March 17, 2025, Plaintiffs objected to the R&R. (Dkt. No. 191). In accordance with 28 U.S.C. § 636(b)(1)(C), the Court must "make a de novo determination of those portions of the [magistrate judge's] report or specified proposed findings or recommendations to which objection [has been] made." After conducting this de novo review, the Court may "accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge." *Id.*; *see* Fed. R. Civ. P. 72(b)(3).

I. DISCUSSION

Plaintiffs' objections to the R&R can be grouped into two categories: (1) objections related to design-defect claims and (2) objections related to failure-to-warn claims. (Dkt. No. 191 at 4–13). The Court finds these objections unpersuasive.

A. DESIGN-DEFECT OBJECTIONS

Plaintiffs contend that Judge Palermo misapplied preemption jurisprudence to their design-defect claims, arguing that the R&R overlooks the connection between

Defendants' federal reporting obligations and the continued use of a defective design. (*Id.* at 4–6). They also challenge Judge Palermo's conclusion that their proposed alternatives to Filshie Clips are not "safer and feasible" design alternatives under Texas law. (*Id.* at 6) (quoting Dkt. No. 190 at 10).

Judge Palermo correctly determined that the design-defect claims are preempted because Plaintiffs do not allege that the Filshie Clips were designed in violation of federal standards. (Dkt. No. 190 at 8). Instead, their theory essentially challenges an FDA-approved design as unreasonably dangerous, (*see* Dkt. No. 40 at 17–18)—precisely the type of claim the FDA's preemption provision prohibits. *See* 21 U.S.C. § 379r(a). As Judge Palermo explained, permitting such a design-defect claim "would necessarily allow state law to impose requirements on the device that add to or differ from those imposed by federal law." (Dkt. No. 190 at 8).

And although Plaintiffs argue that there is a causal connection between Defendants' alleged violation of federal reporting requirements and the continued use of a defective design, (Dkt. No. 40 at 9–10, 17–18); (Dkt. No. 191 at 5), they don't explain how this connection saves their design-defect claims from preemption, (*see* Dkt. No. 191 at 4–6). Their objections merely assert this connection without establishing how it creates a parallel claim under Texas law that is not subject to federal preemption. (*See* Dkt. No. 190 at 9) (explaining why "Plaintiffs' attempt to connect their claim to the adverse event reporting requirement is also impliedly preempted under § 337(a)" (internal docket citations omitted)).

The Court also agrees with Judge Palermo's assessment that Plaintiffs' proposed alternative designs—cauterization of fallopian tubes and salpingectomy—are entirely different procedures rather than safer alternatives to the Filshie Clip itself. (*Id.* at 9–10). As the R&R notes, Texas law requires plaintiffs to propose a safer and feasible alternative design to the alleged defective design, not entirely different procedures. (*Id.* at 10) (citing *Pizzitola v. Ethicon, Inc.*, No. 4:20-CV-02256, 2020 WL 6365545, at *4 (S.D. Tex. Aug. 31, 2020)). For that reason, the Court agrees that "even if Plaintiffs' design defect claim was not preempted, Plaintiffs have failed to establish a genuine issue of material fact exists as to this claim." (*Id.* at 9).

B. FAILURE-TO-WARN OBJECTIONS

Plaintiffs also object to Judge Palermo's finding that their failure-to-warn claims are preempted, arguing that Texas law imposes a parallel duty to report adverse events to the FDA. (Dkt. No. 191 at 6–13). They further assert that Judge Palermo's R&R improperly discounts the Fifth Circuit's opinion in *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011), and does not address the district court's opinion in *Schouest v. Medtronic*, 13 F.Supp.3d 692 (S.D. Tex. 2014). (Dkt. No. 191 at 8–13).

The Court finds that Judge Palermo correctly determined that no parallel duty exists under Texas law to report adverse events to the FDA. (Dkt. No. 190 at 13–17). While federal law requires manufacturers to report adverse events to the FDA, Texas law imposes a duty to warn consumers or prescribing physicians, not a federal regulatory agency. (*Id.* at 13–15). Judge Palermo properly concluded that Plaintiffs' claims based on a failure to report adverse events to the FDA are "simply an attempt by private parties to

enforce" FDA reporting requirements, which is "foreclosed under [21 U.S.C.] § 337(a)." (*Id.* at 16) (quoting *Hawkins v. Bayer Corp.*, No. 1:21-CV-00646, 2022 WL 2761379, at *6 (W.D. Tex. Feb. 1, 2022), *report and recommendation adopted*, No. 1:21-CV-00646, 2022 WL 2718541 (W.D. Tex. Feb. 23, 2022)).

Finally, the Court agrees with Judge Palermo's analysis of the Fifth Circuit's opinion in *Hughes*. (Dkt. No. 190 at 13–15 & 15 n.7). There, a Mississippi statute required manufacturers to provide "adequate warnings or instructions." *Hughes*, 631 F.3d at 769 (quoting Miss. Code § 11-1-63). At the time, Mississippi courts had interpreted this statute as requiring manufacturers to provide reasonable warnings and as allowing claims based on negligence. *See id.* (first citing *Wyeth Labs., Inc. v. Fortenberry*, 530 So.2d 688, 691 (Miss. 1988); and then citing *Bennett v. Madakasira*, 821 So.2d 794, 804 (Miss. 2002)). The plaintiff argued that a jury could use the defendant's alleged violation of federal reporting requirements as evidence that the defendant *also violated* the reasonable-warning requirement of the Mississippi statute. *See id.* at 769–71. The Fifth Circuit did not rule on whether this was a correct interpretation of Mississippi law; instead, "*[a]ssuming* that" the plaintiff's failure-to-warn claim was "based only on [the defendant's] failure to comply with FDA regulations," it held that federal law did not *expressly* preempt the claim. *Id.* at 769 (emphasis added). Thus, *Hughes* stands only for the proposition that *if* Plaintiffs could identify an independent and parallel source of liability in Texas law for noncompliance with federal reporting regulations, then federal law does not *expressly* preempt that claim.

The Court agrees with Judge Palermo that Plaintiffs *have not* identified an independent and parallel source of liability in Texas law for violating federal reporting requirements. (Dkt. No. 190 at 13–17) (citing *Hawkins*, 2022 WL 2761379, at *6). First, at least one Texas court has rejected a parallel common-law duty based on the exact reporting requirement at issue here (albeit in the context of a fraud claim). (*See id.* at 13–14) (citing *Hawkins*, 2022 WL 2761379, at *6); *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127, 137–39 (Tex. App.—Houston [1st Dist.] 2005, pet. denied) (rejecting claim that "failure to make these [adverse event] reports, as required by the FDA, gave rise to a common-law cause of action" under Texas law, and holding that FDA adverse-event reporting regulations do not constitute "a 'parallel federal safety requirement.'")). Second, "Texas courts generally reject arguments that reporting statutes give rise to common-law causes of action under Texas law." (Dkt. No. 190 at 16) (quoting *Hawkins*, 2022 WL 2761379, at *6). Third, Judge Palermo correctly noted that a manufacturer's existing duty to warn extends to consumers under Texas law and to prescribing physicians under the learned-intermediary doctrine —not to federal regulatory agencies. (*Id.* at 13–15).[2]

Finally, Plaintiffs object that Judge Palermo did not discuss the district court's opinion in *Schouest*. (Dkt. No. 191 at 11–13). But *Schouest* adds nothing to Plaintiffs'

[2] What's more, the Texas Supreme Court "continues to exercise extreme caution" when asked to recognize new common-law duties in "highly regulated context[s]." *Hous. Area Safety Council, Inc. v. Mendez*, 671 S.W.3d 580, 596 (Tex. 2023) (Young, J., concurring); *see also id.* at 586–88) (majority opinion) (declining to recognize a new common-law duty in the highly regulated context of private drug testing).

argument. There, while holding that most of the plaintiff's state-law claims were preempted by the FDCA, the court recognized a possible exception to preemption for the plaintiff's "negligence allegation predicated on [the defendant's] failure to submit adverse-event reports to the FDA after the FDA granted the [medical] device premarket approval." *Schouest*, 13 F.Supp.3d at 706. The court held that "*to the extent* Schouest can point to a state law duty to report adverse events," then "this claim *could* escape preemption." *Id.* (emphases added). But the claim ultimately did not escape preemption because—as the district court held in a later order dismissing the claim—"Schouest's amended complaint d[id] not point to a duty to report adverse events" under state law. *Schouest v. Medtronic, Inc.*, 92 F.Supp.3d 606, 609 (S.D. Tex. 2015). So, if anything, *Schouest* cuts against Plaintiffs' argument because there, as here, the plaintiff could not identify a parallel and independent duty under Texas law to report adverse events to a federal agency.

Without an independent basis for liability under state law, Plaintiffs' failure-to-report claims are "'simply an attempt by private parties to enforce' FDA reporting requirements." (Dkt. No. 190 at 16) (quoting *Hawkins*, 2022 WL 2761379, at *6). The claims are therefore impliedly preempted by Section 337(a), which provides that "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353, 121 S.Ct. 1012, 1020, 148 L.Ed.2d 854 (2001) (holding that a private state-law claim is impliedly preempted by the FDCA's public-enforcement provisions if it "exist[s] solely

by virtue of the FDCA disclosure requirements" without an independent basis in state law).

II. CONCLUSION

In accordance with 28 U.S.C. § 636(b)(1)(C), the Court has reviewed de novo those portions of the R&R to which objections have been made and reviewed the remaining proposed findings, conclusions, and recommendations for plain error. The Court agrees with the objected-to portions of the R&R and finds no error in the remaining portions. The Court thus accepts the R&R and adopts it as the opinion of the Court. It is therefore ordered that:

(1) Judge Palermo's R&R, (Dkt. No. 190), is **ACCEPTED** and **ADOPTED** in its entirety as the opinion of the Court;

(2) Defendants' Motions for Summary Judgment, (Dkt. Nos. 123, 124, 125), are **DENIED AS MOOT** as to Plaintiffs' manufacturing-defect claims and **GRANTED** as to all remaining claims;

(3) Defendants' Motion to Exclude, (Dkt. No. 127), is **DENIED AS MOOT**; and

(4) Plaintiffs' Motions for Summary Judgment, (Dkt. Nos. 134, 135), are **DENIED AS MOOT**.

Plaintiffs' claims against Defendants are **DISMISSED WITH PREJUDICE**.

It is SO ORDERED.

Signed on March 25, 2025.

Drew B Tipton

DREW B. TIPTON
UNITED STATES DISTRICT JUDGE